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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,655

09/23/2003

Nyle S. Elliott

A-8601

9116

7590 11/18/2009
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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

11/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,655	Applicant(s) ELLIOTT, NYLE S.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 4, 6, 7 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289) in view of Roe, Donald C. et al. (US 20020019615).

5. Regarding claims 1, 2, 4, 6, 7 and 21-24, Ravo discloses an alert device for detecting the presence of fecal matter (col. 1, lines 39-43, col. 4, lines 1-12, Figs. 1, 2, device 1), comprising:

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6. [1, 24] a pad having an aperture (col. 4, lines 1-12, Figs. 1, 2, support member 3 having cylindrical body portion 7 defining interior space);
7. [1, 24] an alarm attached to said pad (col. 5, lines 25-48, especially lines 25-29);
8. [1, 24] first and second conductors extending from said aperture through said disposable pad to said alarm (col. 5, lines 25-48, especially lines 33-40, electrical circuit, wires not shown; Examiner notes that an electrical circuit requires at least two conductors);
9. [1, 24] a plug (col. 4, lines 1-12, Figs. 1, 2, disc-shaped plug 5);
10. [2] wherein said alarm emits an audible alarm (col. 5, lines 58-62);
11. [4] wherein said alarm emits a tactile alarm (col. 2, lines 62-64, col. 5, lines 25-48, signal transmitted to patient's skin);
12. [6] wherein said plug is secured in said aperture by mating threads (col. 4, lines 33-41, Figs. 1, 2, threaded portions 17 and 23);
13. [7] wherein said pad is a flexible, elastomeric material (cols. 4-5, lines 58-2, 7-13, reticulated polyurethane); and
14. [22] a plug having inner and outer surfaces (col. 4, lines 33-41, Fig. 2, inner surface as depicted below and threaded portion 17).
15. [1, 24] regarding the limitation of an "external" alert device, Ravo teaches at least a portion of the device extending externally from the body (col. 6, lines 10-15, Fig. 2, flange 13 at external skin layer S). Additionally, Ravo calls for an audio alert device (col. 5, lines 58-62, audio signals). A device sending audible signals to a user requires at least a portion to be external of the body, therefore Examiner interprets Ravo as

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suggesting an "external" alert device. The specification does not give special meaning to "external" that would require an entire device to be located externally. Instead, the specification gives examples of a hollow plug and pliable port (§ [0011]), along with a circuit board and power supply (§ [0018], [0020]).

16. Ravo discloses the invention substantially as claimed, see above. However, Ravo lacks third and fourth conductors and an adhesive disposable pad as claimed [1, 21-24].

17. Millot discloses a device for securing an ostomy bag about a stoma and emitting an alarm (col. 2, lines 3-18, col. 3, lines 19-22, Fig. 1, device 1), comprising:

18. [1, 24] an adhesive disposable pad having an aperture (col. 3, lines 23-25, 27-33, Figs. 1 and 2, ostomy seal 5 having through passage 8 and adhesive 12).

19. One would have been motivated to modify support member 3 of Ravo in view of the adhesive 12 of Millot, since Ravo calls for securing a pad to the user's skin (col. 4, lines 24-28, Fig. 2, outer flange 13 adjacent skin). Regarding a limitation of being "disposable," support member 3 of Ravo is capable of being disposed or discarded.

That is, the language "disposable" is interpreted as functional language that requires an element to be disposed. The amendment does not add structure that differentiates from support member 3 of Ravo.

20. Ravo and Millot detect different conditions and alert a user to the presence of fecal matter or moisture in an ostomy device. Ravo detects a distended colon (col. 5, lines 43-48), while Millot senses the moisture content of an ostomy seal (col. 3, lines 60-65). Both place electrical contacts exclusively within a pad member. That is, the

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conductors of Ravo and Millot do not extend to third and fourth conductors. Therefore, both lack third and fourth conductors on a plug as claimed [1, 21-24].

21. A rearrangement of conductors from a pad member to a plug is not sufficient to distinguish over prior art. One would be motivated to modify to conductors of Ravo and Millot to detect wetness or fecal matter in a desired location since the colon may not distend sufficiently to trigger the alarm of Ravo. That is, by extending third and electrical conductors within the plug of Ravo, wastes can be detected within a plug even when a colon does not distend enough to trigger an alarm.

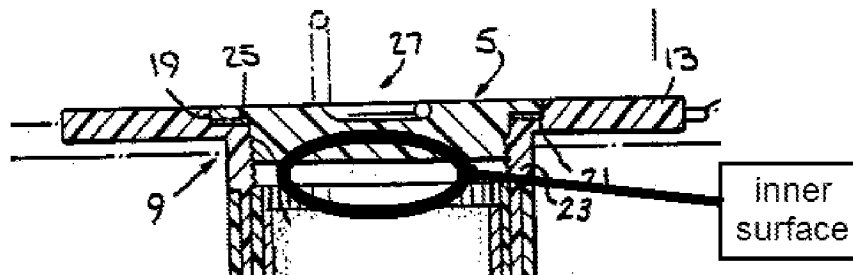
22. Regarding a limitation of third and fourth conductors comprising a pair of spaced apart rings, Millot suggests that ring are a suitable shape for spacing conductors about an aperture (col. 3, lines 39-45, Fig. 2, electrodes 17, 18 on tracks 15 and 16 forming circle arc). The claimed “upwardly extending section” between upper and lower rings of claims 21 and 22, along with the “first section” of claim 23 are interpreted as auxiliary or supporting connections lacking criticality. For example, Ravo expedites disclosure by briefly referring to additional or supplementary or secondary conductors and does not depict them (col. 5, lines 33-40).

23. Additionally, a limitation of a plug having a lumen [claim 22] provides clearance for wastes to contact conductive surfaces. That is, a cylindrical depression or cavity ensures space for wastes to move through the cylinder and contact sensors before reaching the furthest distal edge.

24. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the conductors of Ravo and Millot in order to

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detect wastes that have contacted a plug and not sufficiently distended a colon. See MPEP 2144.04(VI)(C).



Annotated Fig. 2 of Ravo (US 5,108,430)

25. Ravo and Millot disclose the invention substantially as claimed, see above.

However, Ravo and Millot lack a pH sensor as claimed [1, 24]. Roe teaches a diaper (¶ [0022], Fig. 1, diaper 20), comprising a pH sensor (¶ [0043], [0045], [0072], Fig. 1, proactive sensor 60 detecting pH in response to bodily wastes).

26. One would have been motivated to modify the invention of Ravo and Millot as discussed with the pH sensor of Roe, since both Ravo and Millot call for sensing the presence of wastes (Ravo col. 3, lines 31-36; Millot cols. 2-3, lines 65-4).

27. Sensing pH instead of only moisture confirms whether wastes are present. For example, a pH sensor will avoid false alarms from perspiration or humid environments. Here, a pH sensor selectively alerts a user when wastes contact the sensor, instead of sending false alarms that would frustrate the user or caregivers. Significantly, Ravo monitors the conductivity within a lumen in fluid communication with the bowel, which is a humid environment. Therefore, it would have been obvious to modify the invention of Ravo and Millot with the pH sensor of Roe in order to avoid false alarms from other

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moisture sources such as perspiration and naturally occurring humidity. Additionally, Ravo suggests a chemical sensor (col. 5, lines 54-62, chemical sensor detecting intracolonic content).

28. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289) in view of Roe, Donald C. et al. (US 20020019615), further in view of Johnson (US 5266928).

29. Regarding claims 3 and 5, Ravo, Millot and Roe disclose the invention as substantially claimed, see above. However, Ravo, Millot and Roe lack a visible alarm or transmitted signal as claimed [3, 5]. Johnson discloses an alert device wherein the alarm emits a visible alarm or transmits a signal to a remote location (column 8, lines 1-13). Johnson provides the advantage of providing multiple channels to alert a caregiver or user. For example, a user with either impaired vision or hearing may rely more heavily on either audio or visual clues. Transmitting to a remote location provides the advantage of allowing caregivers to leave the user's immediate area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo, Millot and Roe as discussed with the alarms as taught by Johnson in order to alert a caregiver or user effectively.

30. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289) in view of Roe, Donald C. et al. (US 20020019615), further in view of Kim (US 5569216).

31. Regarding claim 8, Ravo, Millot and Roe disclose the invention as substantially claimed, see above. However, Ravo, Millot and Roe lack an inflatable cuff as claimed [8]. Kim discloses an inflatable cuff encircling a plug (column 2, lines 61-67 through column 3, lines 1-2 and Figs. 1-2, external balloon 100). Kim prevents gases and liquids from leaking (col. 1, lines 7-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo, Millot and Roe as discussed with the inflatable cuff as taught by Kim in order to prevent leakage.

32. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289) in view of Roe, Donald C. et al. (US 20020019615), further in view of von Dyck (US 6350255).

33. Regarding claim 10, Ravo, Millot and Roe disclose the invention substantially as claimed, see above. However, Ravo, Millot and Roe lack an absorbent sleeve as claimed [10]. von Dyck discloses an absorbent sleeve disposed about a tube (col. 13, lines 50-57 and Figs. 1-3, bolster 16 comprising foam surrounding catheter 14).

34. Von Dyck provides the advantage of absorbing any waste materials that may bypass sealing means of Ravo. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of

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Ravo, Millot and Roe as discussed with the absorbent sleeve as taught by von Dyck in order to absorb any additional waste materials.

35. Regarding claim 11, Ravo, Millot and Roe disclose the invention substantially as claimed, see above. However, Ravo, Millot and Roe lack a filter as claimed [11]. Von Dyck discloses a plug including a filter (col. 8, lines 38-49, especially lines 47-49, filter (not shown) within port 52 of catheter 14). von Dyck provides the advantage of filtering any flatus gases that are received within a chamber as during normal use Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo, Millot and Roe as discussed with the filter as taught by von Dyck in order to filter flatus gases.

36. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Ravo; Biagio (US 5108430) in view of Millot P et al. (US 6171289) in view of Roe, Donald C. et al. (US 20020019615), further in view of McDonnell (US 4121589).

37. Regarding claim 12, Ravo, Millot and Roe disclose the invention as substantially claimed, see above. However, Ravo, Millot and Roe lack an adhesive ring as claimed [claim 12]. McDonnell discloses an adhesive ring attached to one side of a pad (col. 3, lines 54-56 and Fig. 1, adhesive material 9). McDonnell provides the advantage of providing additional sealing force between a user and waste collection device.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ravo, Millot and Roe as discussed with

the adhesive ring as taught by McDonnell in order to provide additional sealing force. In this modification, adhesive material 9 is placed about an outer flange 13 of Ravo.

Response to Arguments

38. Applicant's arguments, see p. 6-7 filed 01 September 2009 with respect to the rejection(s) of claim(s) 1-8,10-12 and 21-24 under 35 USC § 103 over Ravo, Millot, Johnson, Kim, von Dyck and McDonnell have been fully considered and are persuasive. Therefore, the rejection is withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Ravo, Millot, Roe, Johnson, Kim, von Dyck and McDonnell.

39. Applicant asserts that Ravo lacks first and second conductors extending from the aperture to the alarm, since one of the electrodes that close the circuit (43) is in contact with the patient's skin. Applicant notes that in the immediate invention, all electric circuitry goes inside the pad and none of the electric parts contact the patient's skin. Examiner interprets the language "extending from said aperture through said disposable pad" broadly to include the conductors passing through support member 3 of Ravo. Additionally, Ravo discloses an embodiment connecting a pressure transducer within support member 3 (col. 5, lines 49-58, Figs. 1, 2 electrical contact connecting pressure transducer within layer 29). Here, at least two electrical connectors pass through the aperture support member 3 (interpreted as the claimed pad), to connect with a sensor.

40. Applicant contends that Ravo lacks a plug as claimed, since the Ravo plug is disk-shaped and secures to the outside of the patient on the stoma surface. Applicant's

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plug is a cylindrical shaped plug that goes inside the stoma. The alarm method disclosed in the Biagio reference uses a skin contacting electrode to generate a signal. Applicant's claimed invention does not have any skin contacting electrodes to generate a signal. The signal is generated outside the body of the patient. Examiner notes that the claims do not preclude a disc-shaped plug, and that plug 5 of Ravo is substantially cylindrically shaped, since it is circular and fits within the lumen of support member 3. Additionally, Ravo calls for an audio alarm (col. 5, lines 58-62), similar to the immediate invention. An audio alarm requires at least an external component for a user to hear to signal.

41. Applicant notes that Ravo lacks an adhesive patch., since Ravo instead has a tube retained within the stoma. Examiner cites Millot as teaching an adhesive pad in the new grounds of rejection, and finds motivation to modify Ravo in view of Millot since Ravo calls for securing external flange 13 to the skin (col. 6, lines 10-15, Figs. 1, 2).

42. Applicant finds that Millot fails to remedy the deficiencies of Ravo, namely connectors inside a pad. Applicant reasons that Millot instead indicates whether a pad is wet and that the electrodes are part outside the pad. Examiner interprets connectors inside a pad" broadly as including the conductors of Millot embedded within the material of the Millot pad. That is, the claims do not require conductors insulated within a pad, or preclude conductors from also being in contact with an external environment.

43. Applicant reasons that the Millot pad serves a different purpose, since it secures an ostomy bag. Examiner instead cites Ravo as teaching the claimed plug.

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44. None of Ravo, Millot, Johnson, Kim, von Dyck or McDonnell discloses a pH sensor, therefore Examiner cites Roe as teaching a pH sensor in the new grounds of rejection. Additionally, Examiner cites Millot as teaching an adhesive pad.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Springer; John S. et al. US 6617488
- ◆ Nair; Rajesh M. US 5568128
- ◆ Essen-Moller; Anders US 5479935
- ◆ Di Scipio; William J. US 4977906
- ◆ Lassen; Per W. US 4205671
- ◆ Mahoney; Kurt US 4106001
- ◆ Bloom; Stanley US 3971371

46. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

47. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

48. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich

Tel 571-272-2590

Fax 571-273-2590

49. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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51. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 November 2009